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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/682,371	10/09/2003	Randy Westlund	GUID.077PA	6103

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EXAMINER	
STOKLOSA, JOSEPH A	

ART UNIT	PAPER NUMBER
3762	

NOTIFICATION DATE	DELIVERY MODE
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	**Application No.** 10/682,371	**Applicant(s)** WESTLUND ET AL.
	Examiner JOSEPH STOKLOSA	**Art Unit** 3762

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *26 April 2010*.
2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.
3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-26* is/are pending in the application.
  4a) Of the above claim(s) _____ is/are withdrawn from consideration.
5)☐ Claim(s) _____ is/are allowed.
6)☒ Claim(s) *1-26* is/are rejected.
7)☐ Claim(s) _____ is/are objected to.
8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.
10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.
  Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
  Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  a)☐ All b)☐ Some * c)☐ None of:
    1.☐ Certified copies of the priority documents have been received.
    2.☐ Certified copies of the priority documents have been received in Application No. _____.
    3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
  * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
  Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413)
  Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Response to Arguments

1. Applicant's arguments, see Remarks, filed 4/26/2010, with respect to Claims 1-26 have been fully considered and are persuasive. The Non-Final Rejection of 1/26/2010 has been withdrawn.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 1, 3-4, 7-14, and 18 are rejected under 35 U.S.C. 102(b) as being anticipated by Stokes et al. (US 5,443,492).

4. Stokes discloses a medical lead introducer system comprising; advancing a lead introducing system (e.g. introducer assembly seen in Fig. 4), through the pericardium to access and penetrate the myocardium (e.g. Col. 3, line 39- Col. 4, line 5). Stokes discloses the lead is passed through the introducer into the myocardium and actively fixated with the lead hook to implant the electrode in the myocardium and the splitable needle/introducer is removed (e.g. Col. 3, line 61-Col. 4, line 5).

5. With regard to claim 3-4, Stokes discloses a hollow needle that penetrated the myocardium, and Examiner considers space to be created in the hollow needle chamber (e.g. needle 40).

6. With regard to claim 10-11, Stokes discloses the active fixation hook to be helical about the lead body (e.g. ABSTRACT).

7. With regard to claim 12, Stokes discloses the fixation hook is proximal to the distal tip electrode (e.g. Fig. 1).

8. With regard to claim 18, Stokes discloses penetrating the myocardium to a predetermined depth, and discloses an angled needle point such that the myocardium is penetrated at a shallow angle (e.g. needle angle seen in Fig. 4 and Col. 7, line 22-42).

Claim Rejections - 35 USC § 103

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

10. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

11. Claims 15-17 and 19-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Stokes as applied above.

12. With regard to claims 15-17, Stokes fails to explicitly various active fixation members such as a clip, chronic fixation, and sutures. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the system as taught by Stokes with at least trying fixation members such as a clip, chronic fixation, and sutures since the use of a clip, chronic fixation, and sutures are all known to provide the know result of efficiently fixating an electrode lead and the selection of any of these well known fixation members would therefore be within the level of ordinary skill for a worker in the art.

13. With regard to claim 19, Stokes discloses the invention as claimed including tangentially piercing the myocardium, but fails to explicitly teach the angle of insertion to be within 5-45 degrees and a depth of 1-10mm. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the method as taught by Stokes with an angle of entry between 5-45 degrees and an insertion depth between 1-10mm since such a modification would provide the predictable results of reducing trauma to the myocardial surface of the heart and ensuring the proper depth of insertion to effectively position the electrode. Further, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the system as taught by Stokes with an insertion angle between 5-45 degrees and a depth of 1-10mm, since it has been held that where the general conditions of a claim are disclosed

in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller,* 105 USPQ 233.

14. With regard to claim 20, Stokes discloses the invention as claimed but fails to teach accessing the left ventricle. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the method as taught by Stokes with accessing the left ventricle, since such a modification would provide the predictable results of accessing the heart chamber that provides for pumping oxygenated blood and most responsible for systolic hemodynamic and cardiac failure, where application of the electrode lead for pacing would provide pacing to the left ventricle to treat cardiac failure.

15. Claims 2, 5-6, 21-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Stokes in view of Yokoyama (US 4,317,458).

16. Stokes discloses the invention as claimed but fails to explicitly teach a dilating sheath. Yokoyama discloses the use of a dilating sheath as set forth in Col. 2, line 1 for providing the predictable results of creating space for lead passage and maintaining the opening created by the distal needle/point. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the system as taught by Stokes with using a dilating sheath, as taught by Yokoyama, since such a modification would provide the predictable results of creating space for lead passage and maintaining the opening created by the distal needle/point.

17. Examiner further considers the equivalency of using a dilating sheath with a needle and the use of a hollow needle assembly for creating space when piercing and

passing through tissue and the selection of any of the assemblies to perform the method of creating space upon piercing tissue would be within the level of ordinary skill in the art. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the method as taught by Stokes with selecting a needle with a dilation sheath to pierce tissue and create space for lead passage.

18. With regard to claim 2, Stokes discloses the invention as claimed but fails to explicitly teach using a catheter to gain access to the epicardium from an outer chest wall. Yokoyama teaches that it is known to gain access through an outer chest wall as set forth in Col. 2, line 43-45 for providing the predictable results of a minimally invasive procedure to reduce patient discomfort and time by providing a substantially direct access point. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the system as taught by Stokes with using a catheter to gain access to the epicardium from an outer chest wall since such a modification would provide the predictable results of a minimally invasive procedure to reduce patient discomfort and time by providing a substantially direct access point.

Conclusion

19. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Kaplan et al. (US 2003/0212446) teaches that it is known to use a guide wire and needle where a lead is passed over the guide wire through a lead lumen. Examiner has cited this as evidenced that such a system/method is known in the art but has not relied upon it for the basis of rejecting any claims.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JOSEPH STOKLOSA whose telephone number is (571)272-1213. The examiner can normally be reached on Monday-Friday 7:30-4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Niketa Patel can be reached on 571-272-4156. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Niketa I. Patel/
Supervisory Patent Examiner, Art Unit 3762

Joseph Stoklosa
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Examiner, Art Unit 3762
1/14/2010